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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,989

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EXAMINER

VERMA, RISHI GOPAL

ART UNIT

PAPER NUMBER

3728

MAIL DATE

DELIVERY MODE

07/19/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/575,989	Applicant(s) JEMELIN ET AL.	
	Examiner RISHI VERMA	Art Unit 3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 34-37, 39-43, 45-55, 57, 58, 60 and 61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-33, 38, 44, 53, 56 and 59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/17/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/17/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 34-37, 39-43, 45-55, 54-55, 57-58, 60-61 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species 2-4, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/5/2010.
2. Applicant's election without traverse of Species 1 drawn to Figures 3-4C in the reply filed on 2/5/2010 is acknowledged.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: It is unclear what the limitation "transportation" in claim 38 line 2 means.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 32 lines 4-5 recites the limitation "the ampoule to snap engage into a groove of the ampoule." It is not clear whether the ampoule can snap engage with itself.

Correction is required.

Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 recites the limitation "transportation" in line 2 and line 3. It is not clear what does the term "transportation" means. Examiner considers limitation " transportation" as a cap. Correction is required.

1. Regarding claims 28-33, 38, 44, 53, 56, 59 the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

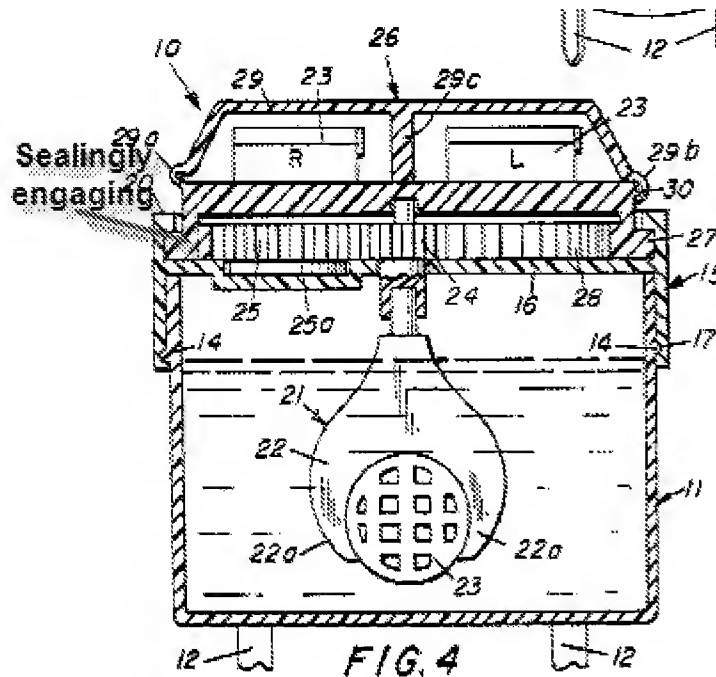
Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.



Claims 28, 29, 30, 31, 38, 44 are rejected under 35 U.S.C 102 (b) as being unpatentable over Dolphin G. Frantz (U S Patent No.: 3623492).

Regarding claim 28, the examiner considers the means for releasing connecting (Specification, page 7, lines 8-10) to invoke 112 6th paragraph.

Dolphin G. Frantz discloses a package as illustrated in Fig. 4 capable of preserving a medical device 23 comprises an external capsule 11 and a cap 26 sealingly engaging as labeled above in Fig. 4 the external capsule 11, wherein a means is providing for releasingly (Dolphin G. Frantz, column 1, lines 21-23 is functionally equivalent to Means for releasing connecting) connected the medical device 23 with the

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cap 26 upon removing the cap and the medical device from the external capsule as illustrated in Fig. 1.

Regarding claim 29, Means is adapted for releasing connecting (Specification, page 7, lines 27-28) invokes 112 6th paragraph.

Dolphin G. Frantz discloses an ampoule 20 capable of holding the medical device 23, wherein the means is adapted for releasingly connecting (Dolphin G. Frantz, column 1, lines 27-30 is functionally equivalent to Means is adapted for releasing connecting) the ampoule with the cap as illustrated in Fig. 4 upon removing the cap and the ampoule from the external capsule as illustrated in Fig. 1.

Regarding 30, Means for releasing connecting (Specification, page 8, lines 22-25) invokes 112 6th paragraph.

Dolphin G. Frantz discloses wherein the means for releasingly connecting (Dolphin G. Frantz, column 1, lines 60-61 is functionally equivalent to Means for releasingly connecting) the ampoule with the cap comprises a snap coupling as labeled above in Fig. 1 between the ampoule and the cap, the snap coupling being releasable in an axial direction of the external capsule as illustrated in Fig. 1.

Regarding claim 31, Means is adapted for releasing connecting (Specification, page 8, lines 1-5) invokes 112 6th paragraph.

Dolphin G. Frantz discloses wherein the means for releasably connecting (Dolphin G. Frantz, column 1, lines 32-35 is functionally equivalent to Means for releasably connecting) the ampoule with the cap comprises an actuation knob as labeled above in Fig. 1.

Regarding claim 38, It is noted that the terminology “ transportation means” does not invoke the provisions of 35 USC 112 6th paragraph MPEP 2181.

Dolphin G. Frantz discloses a medical device 23 comprises an external capsule 11, a cap 26 sealably engaging as labeled above in Fig. 4 the external capsule 11, and a transport means 26 surrounded by the cap 26 and extending therein, wherein the transport means is adapted for releasably as illustrated in Fig. 1 connecting to the medical device 23.

Regarding claim 44, Means is adapted for releasing connecting (Specification, page 7, lines 8-10) invokes 112 6th paragraph.

Dolphin G. Frantz discloses a medical device 23 comprises an external capsule 11, a cap 26 engaging as illustrated in Fig. 4 the external capsule 11 and a sealing means closing an open end of the capsule as illustrated in Fig. 4, wherein a means is provided for releasably (Dolphin G. Frantz, column 1, lines 21-23 is functionally equivalent to Means for releasing connecting) connecting the medical device 23 with the cap 26 upon removing the cap and the medical device from the external capsule as illustrated in Fig. 1.

Claims 28, 38, 44 are rejected under 35 U.S.C 102 (b) as being unpatentable over Shumutz et al. (U.S. Patent No.6261097 B1).

Regarding claim 28, the examiner considers the means for releasing connecting (Specification, page 7, lines 8-10) to invoke 112 6th paragraph.

Shumutz et al. discloses a package as illustrated in Fig. 4 capable of preserving a medical device 23 comprises an external capsule 11 and a cap 26 sealingly engaging as labeled above in Fig. 4 the external capsule 11, wherein a means is providing for releasingly (Shumutz et al, column 1, lines 18-19 is functionally equivalent to Means for releasing connecting) connected the medical device 23 with the cap 26 upon removing the cap and the medical device from the external capsule as illustrated in Fig. 1.

Regarding claim 38, It is noted that the terminology “ transportation means” does not invoke the provisions of 35 USC 112 6th paragraph MPEP 2181. Shumutz teaches the invention as claimed, and Shumutz further teaches an external capsule 300, a cap 320 sealingly engaging the external capsule as labeled above in Fig. 5, and a transport 320 means (Dolphin G. Frantz, column 8, lines 32 -35) surrounded by the cap and extending therein, wherein the transport means is adapted for releasingly connecting to the medical device as illustrated in Fig. 5. It is noted that the terminology “ transportation means” does not invoke the provisions of 35 USC 112 6th paragraph MPEP 2181

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Regarding claim 44, the examiner considers the means for releasing connecting (Specification, page 7, lines 8-10) to invoke 112 6th paragraph.

Shumutz discloses a package for preserving a medical device comprising an external capsule 300, and a cap 320 engaging as labeled above Fig. 5 closing an open end of the capsule as illustrated in Fig. 8B, wherein a means is providing for releasingly (Shumutz et al, column 1, lines 18-19 is functionally equivalent to Means for releasing connecting) connecting the medical device with the cap upon removing the cap and the medical device from the external capsule as illustrated in Fig. 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 29, 30, 31, 32, 33, and 53 are rejected under 35 U.S.C. 103(a) as being obvious over Shumutz et al. (U.S. Patent No.6261097 B1) in view of Yen (U S Patent No.: 3999434).

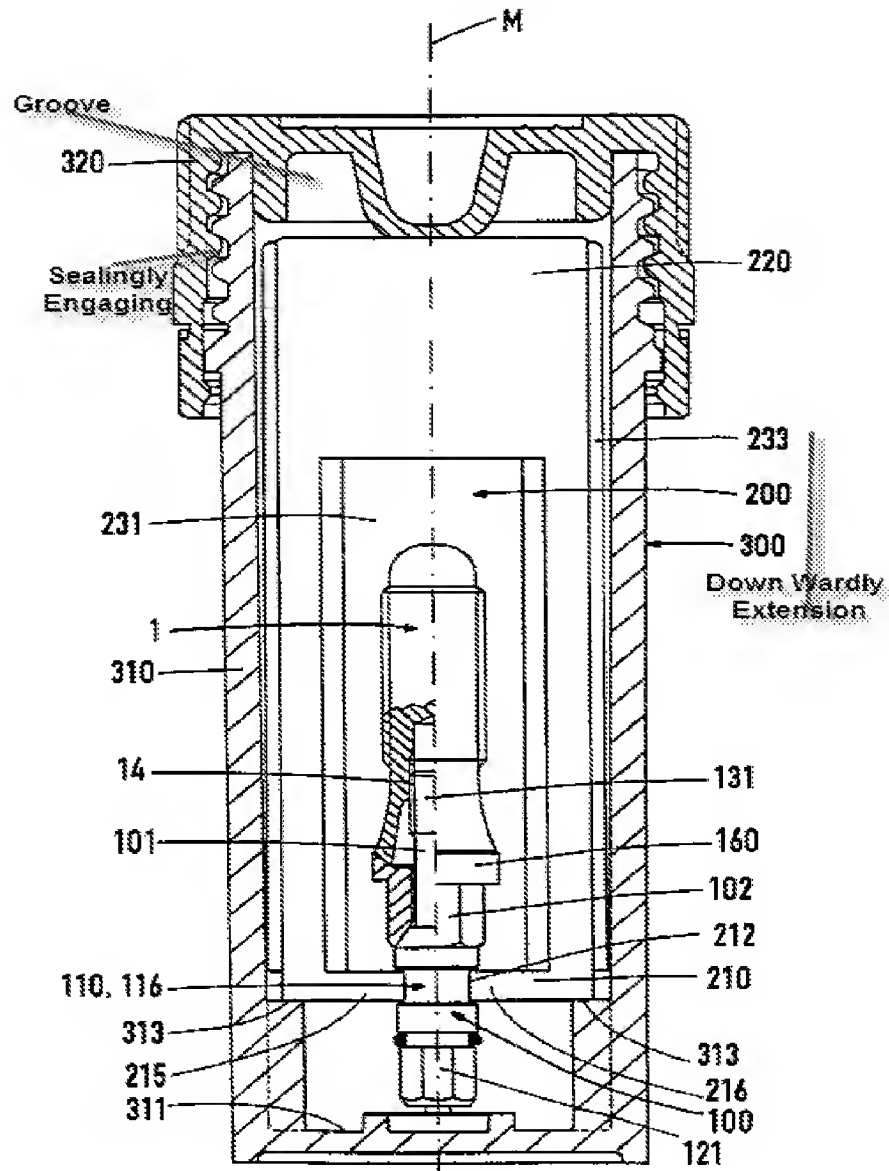


FIG. 5

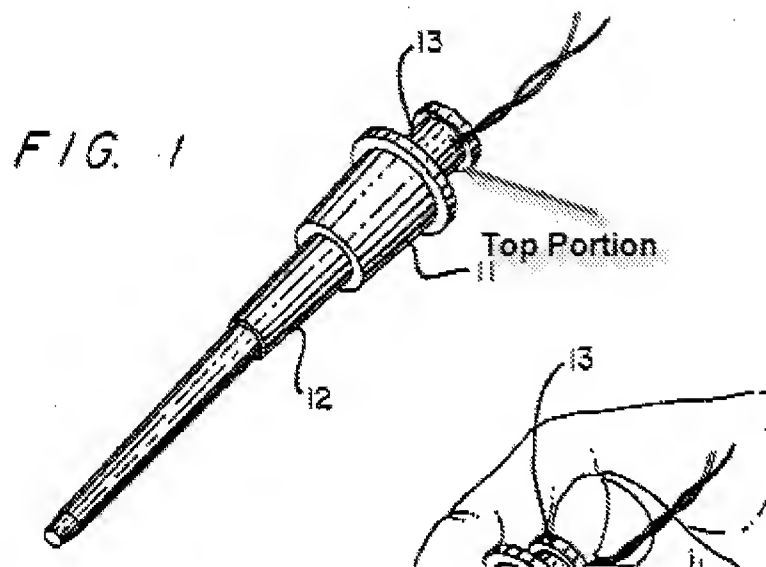
Regarding claim 29, Shumutz teaches the invention as claimed, and Shumutz further teaches an ampoule 220 capable of holding the medical device 1. However, Shumutz does not teach wherein the means is adapted for releasably connecting the ampoule

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with the cap upon removing the cap and the ampoule from the external capsule. The previous problem with the packaging was that the ampoule 200 with an implant 1 used to get tipped out of the external cylinder. Means is adapted for releasing connecting (Specification, page 8, lines 22-25) invoke 112 6th paragraph. Yen does teach an ejector 13 as a means adapted for releasably connecting (Yen, column 2, lines 20-24 is functionally equivalent to Means is adapted for releasably connecting) the probe cover 12 with end 14 in order to use the probe (Yen, column 3, lines 6-10). It would have been obvious to one of the ordinary skills in the art at the time of the invention to modify the cap 320 of Shumutz by adding an ejector 13 as taught by Yen in order to keep the ampoule from falling off the cap because it has been held that combining prior art elements according to known methods to yield predictable results would have been an obvious extension to prior art teachings, KSR , 550 U.S. at ----, 82 USPQ2d at 1396, MPEP 2114 III A.

Regarding claim 30, the examiner considers the means is adapted for releasably connecting (Specification, page 7, lines 27-28) invoke 112 6th paragraph.

Shumutz teaches the invention as claimed; and Shumutz further teaches means for releasably connecting (Yen, column 10, lines 19-20 is functionally equivalent to Means for releasably connecting) the ampoule with a cap comprises a snap fitting as illustrated Fig. 8B between the ampoule and the cap, the snap coupling being releasable in an axial of external capsule.



Regarding claim 31, Shumutz teaches the invention as claimed. However, Shumutz does not teach the means for releasably connecting the ampule with the cap comprises an actuating knob. Means is adapted for releasably connecting (Specification, page 8, lines 1-5) invoke 112 6th paragraph. Yen teaches the means for releasably connecting (Yen, column 3, lines 6-10 is functionally equivalent to Means for releasably connecting) the probe cover 12 with a top portion as labeled above Fig. 2 comprises an actuating knob 13 (Yen, column 1, lines 34-37) in order to release the probe cover. It would have been obvious to one of the ordinary skills in the art at the time of the invention to modify the cap 320 of Shumutz with an actuating knob 13 as taught by Yen in order for the user to easily release the cap with ampoule from the external container because it has been held that combining prior art elements according to known methods

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to yield predictable results would have been an obvious extension to prior art teachings, *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396, MPEP 2141III A.

Regarding claim 32, Shumutz teaches the invention as claimed, and Shumutz further teaches the cap 320 is threadingly engaged as illustrated in Fig. 8A with the external capsule 310 and includes a downward extension which as labeled above in Fig. 5, in an assembled state of the package protrudes between the external capsule and the ampoule to snap engages into a groove of the ampoule as illustrated in Fig. 5.

Regarding claim 33, Shumutz teaches the invention as claimed. However, Shumutz does not teach a axially depressing knob operatively connected to the top portion of the cap the downward extension of the cap becomes disengaged from a circular groove of the ampoule, there by separating from the cap and top portion made out of elastic material. Yen teaches an actuating knob 13 as illustrated in Fig. 2 operatively connected to the top portion that is used to release the probe cover 12 in order to measure the temperature. It would have been obvious to one of the ordinary skills in the art at the time of the invention to modify the cap 320 of Shumutz adding a actuating knob as taught by Yen in order for the user to easily release the ampoule from the cap because it has been held that combining prior art elements according to known methods to yield predictable results would have been an obvious extension to prior art teachings, *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396, MPEP 2141III A.

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However, Shumutz does not teach a top portion of the cap made out of a elastic material. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the top portion of the cap to be made out of any material such as plastic or resilient material because it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability (example: to make it stronger) for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claim 53, Shumutz teaches the invention as claimed, and Shumutz further teaches a medical device is a dental implant which is held within the ampoule as illustrated in Fig. 5.

Regarding claims 56, 59 are rejected under 35 U.S.C. 103(a) being unpatentable over Shumutz et al. (U.S. Patent No.6261097 B1), as applied to claim 28.

Regarding claim 56, Shumutz does not teaches the invention as claimed, and Shumutz further teaches an external capsule 300 with exception an aqueous solution. It would have been obvious to one of the ordinary skills in the art at the time of the invention to pour bottled water which is considered an aqueous solution, as a matter of obvious extension of prior art teachings.

Regarding claim 59, Shumutz does not teaches the invention as claimed, with exception of cyclo-olefin copolymer material. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the top portion of the cap to be made out of any material such as cyclo-olefin copolymer, high density polyethylene or resilient material because it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability (example: to make it stronger) for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RISHI VERMA whose telephone number is (571)270-1390. The examiner can normally be reached on Monday-Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ehud Gartenberg can be reached on 571-272-4828. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RISHI VERMA/
Examiner, Art Unit 3728